

REMARKS

The claims have been amended in order to more completely describe and distinctly claim the invention and to overcome the various grounds of rejection set forth in the Official Letter. Inasmuch as no new matter is embodied by the proposed amendments, entry thereof is respectfully requested.

The Examiner's objection to the Abstract is noted. It is respectfully requested that the requirement for correction be postponed until an indication of allowable subject matter that will allow an amendment of the Abstract to accord with the allowable subject matter.

The objection to the specification (paragraph 4) and the rejection of claim 1 (paragraph 6A) under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention, is believed to be obviated by the above amendment, whereby "-NH-" has been inserted into the definition of "W". Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1 (paragraph 6B) and claims 3-7 (paragraph 6C) under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention, is believed to be obviated by the above amendment, whereby the Examiner's suggestions for amending the claims to overcome the grounds of rejection have been effected. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 8-13 (paragraph 6D) under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention is respectfully traversed. The Examiner states that the "claims are silent about the nature of the article, manufacturing step/process for the article and the nature of the pharmaceutical agent". The nature of the article is expressed in the definition thereof as a "packaging material" for a

pharmaceutical agent. It is respectfully submitted that those skilled in the art would be well aware of what is intended by such a definition. Applicant is aware of no requirement that a claim to an article set forth the method of its manufacture. In any event the skilled artisan would be well aware of how to prepare a package for a pharmaceutical agent. The nature of the pharmaceutical agent is defined as the compounds of claim 1.

Finally, the Examiner's attention is directed to U.S. patents 4,988,710 and 5,011,853 which contain claims similar to those presented herein and which define the elements of the claimed "article of manufacture" essentially in the same manner. It is respectfully submitted that the present claims, like those of the above-cited patents satisfy the requirements of 35 USC §112, second paragraph. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims under 35 USC §112, first paragraph, on the ground that the specification does not enable the claims is respectfully traversed. The Examiner's rejection is based on the conclusion that one skilled in the art would not expect that the various conditions stated to be relieved by the claimed invention would be ameliorated by the same class of compounds and cites several publications to support this contention. These publications, however, actually support the proposition that the claimed compounds would function as claimed since all act on the same receptor, an action stated by the cited publications to be essential for the activities postulated. Attention is also directed to the disclosures of US patents 6,593,367; 6,541,520; 6,323,239; 6,566,400; 6,562,364 and 4,843,071, all of which establish that those skilled in the art are well aware that the discovery of compounds useful for the treatment of addiction are indeed useful for the treatment of a wide assortment of such addictive behaviors, including opiate, nicotine, alcohol and other drug addictions as well as eating disorders.

The Examiner's rejection appears to be primarily based on the premise that some experimentation would be required by one skilled in the art to practice the claimed invention. Attention is directed to the decision in *Syntex v. Paragon Optical*, 7 USPQ2d 1001 which states the applicable regarding the interpretation of the "enablement requirement" of 35 USC§112 as follows:

“---A patent's disclosure complies with 35 U.S.C. §112 if it defines the desired functional relationship even if some experimentation is required to reproduce the invention. Patent claims that include some claimed combinations which are inoperative are not necessarily invalid under 35 U.S.C. §112. *Atlas Powder Co. v. E. I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577 [224 USPQ 409, 414] (Fed. Cir. 1984); *In re Dinh-Nguyen*, 492 F.2d 856, 858-59 [181 USPQ 46,48] (C.C.P.A. 1974); *In re Anderson*, 471 F.2d 1237, 1242 [176 USPQ 331, 335] (C.C.P.A. 1973). It is impractical and unreasonable to require a patentee to set out an extended list of precise combinations and formulae since one skilled in the art would avoid obvious inoperative combinations. *Ex parte Cole*, 223 USPQ 94 95—96 (TTAB 1983) *Lever Bros. C'o. v. Procter & Gamble Mfg. Co.*, 139 F.2d 633 638 [60 USPQ 76, 80—81] (4th Cir. 1943); *In re Kroekel*, 504 F.2d 1143, 1146 [183 USPQ 610, 612] (CCPA, 1974).”[I]t is not a function of the claims to specifically exclude . . . possible inoperative substances.” *Atlas Power Co.* 750 F.2d at 1576 [224 USPQ at 414]---”

In light of the above-discussed authorities, therefore, since the specification sets out an art-recognized community of disorders that are known by those skilled in the art to be treatable by compounds having an effect on the receptors identified in the specification, the claims are enabled thereby; even though some experimentation may be required to establish optimum parameters for a particular application.

Attention is also drawn to the decision in *Ex parte Reese*, (unpub), 40 USPQ2d 1221, citing *In re Armbruster*, 185 USPQ 152 and *In re Marzocchi*, 169 USPQ 367, which held:

“---It is incumbent upon the (Examiner) whenever a rejection on this basis [lack of enablement] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement---”(emphasis the Board's)

In the present case the Examiner has only cited several references that actually support the applicant's case since they recognize the above discussed "community of addictive" behaviors that are commonly recognized by those skilled in the art to be treatable by compounds known to have an effect on the receptor(s) identified by the instant specification. While it is true that the references cited by the Examiner indicate that different amounts of the drugs discussed in the articles may be required for the treatment of the various conditions mentioned, the fact remains that the community of disorders is well recognized. Determining the optimum dosage for each condition treated is well within the skill of the art and is certainly not indicative of a lack of enablement. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1 and 3-13 under 35 USC 102 over Prokai et al as being completely anticipated is respectfully traversed. The reference was co-authored by the applicant and several others who worked under the direction and supervision of the applicant and sole inventor of the present invention, and participated in discussions during the course of experiments relating to the invention, but who did not contribute to the conception or completion of the invention described and claimed herein. A declaration attesting to the foregoing is attached hereto.

The cited reference was published (i.e., made part of the public domain) less than one year prior to the filing date of the present application. Under the decision in *Ex parte Katz*, 215 USPQ 14, therefore, the reference is not a statutory bar against the present claims under 35 USC §102(a) since it does not reference the work or invention "of another". Accordingly, withdrawal of this ground of rejection is respectfully requested.

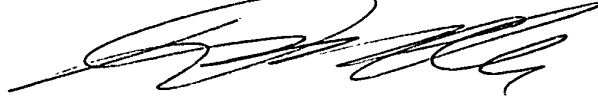
The rejection of claims 1-13 over 35 USC 103 as obviously unpatentable over Tan et al in view of Prokai et al is also respectfully traversed. The article by Prokai et al is unavailable as a reference against the present claims for the reasons set forth above.

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Inasmuch as Tan et al does not anticipate or suggest all of the elements of the claims, as noted by the Examiner, withdrawal of this ground of rejection is respectfully requested. Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

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